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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,902	01/16/2004	Fiorenzo Stirpe	PNJ-005CN	7360

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

SWOPE, SHERIDAN

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/758,902	Applicant(s) STIRPE ET AL.	
	Examiner Sheridan L. Swope	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 and 27-36 is/are rejected.
- 7) ☐ Claim(s) 15 and 32-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>0906</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response of July 18, 2006, to the First Action on the Merits of this case, mailed April 18, 2006, is acknowledged. It is acknowledged that Claims 1-10 and 21-26 have been cancelled, Claims 11-15 and 17 have been amended, and Claims 27-36 have been added. Claims 11-20 and 27-36 are pending. New Claims 27-36 are deemed to be encompassed by the elected invention, a polynucleotide encoding a ribosome-inactivating protein. Claims 11-20 and 27-36 are hereby examined.

Information Disclosure Statement

JP-1-272599 listing on the Information Disclosure Statement filed September 19, 2006 has not been considered because it is in Japanese. If Applicants wish for JP-1-272599 to be considered, a translation should be submitted.

Claims-Objections

Objection to the claim set for not beginning with a sentence of which the claims are an object e.g., "We claim" or "The claims are", is maintained.

Claim 15, line 7, is objected to for "an", which should be corrected to "a".

Claims 32 and 35 are objected to for "an amino acid amino acid sequence", which should be corrected to "an amino acid sequence".

Claims 32-36 are objected to for "claims", which should be corrected to "claim".

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 32 and 35 are rendered indefinite by the phrase “wherein the ribosome-inactivating protein an amino acid sequence”. It is unclear whether said phrase is meant to be “wherein the ribosome-inactivating protein comprises an amino acid sequence”, “wherein the ribosome-inactivating protein consists of an amino acid sequence”, or some other phrase. Clarification is required. For purposes of examination, it is assumed that the phrase is meant to be “wherein the ribosome-inactivating protein consists of an amino acid sequence”.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 11-20 under 35 U.S.C. 112, first paragraph lack of enablement, for the reasons stated in the prior action, is maintained. In addition, new Claims 27-36 are herein rejected under 35 U.S.C. 112, first paragraph lack of enablement, for the same reasons.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. The test for enablement is whether one skilled in the art could make or use the claimed invention without undue experimentation. The specification provides an amino acid

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sequence of a novel type-1 ribosome-inactivating protein and provides alignment of said protein with 15 other known ribosome-inactivating proteins. The specification also describes standard techniques for making fusion protein, making and expressing polynucleotide, and testing polypeptides for ribosome-inactivating protein activity. Thus, only routine experimentation would be required to practice the recited invention.

These arguments are not found to be persuasive for the following reasons. The specification fails to provide the complete sequence of any polypeptide comprising SEQ ID NO: 1 or SEQ ID NO: 9, wherein the polypeptide has ribosome-inactivating activity. Relevant to the instant invention, the specification also fails to disclose any polynucleotide encoding any polypeptide comprising SEQ ID NO: 1 or SEQ ID NO: 9, wherein the polypeptide has ribosome-inactivating activity. Furthermore, Applicants' subsequent publication teaches that the full-length, active protein is 250 amino acids long, having active site residues E¹⁶⁵ and R¹⁶⁸ (den Hartog et al, 2002; Fig 1, pg 1776, para 2). The specification fails to teach the active, full-length protein or the active site residues or any polynucleotide encoding such. The specification also fails to teach which residues of any active polypeptide can or cannot be altered and still retain the desired activity. While it is acknowledged that techniques for making fusion proteins, making and expressing polynucleotides, testing polypeptides for ribosome-inactivating protein activity are standard in the art, to make and test the full-scope of the recited polynucleotides for encoding polypeptides having ribosome-inactivating activity, with no guidance as to the relationship between the structure of a polypeptide and the function of ribosome-inactivating activity, clearly represents undue experimentation.

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For these reasons and those explained in the prior action, Claims 11-20 and 27-36 are rejected under 35 U.S.C. 112, first paragraph for lack of enablement, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Written Description

Rejection of Claims 11-20 under 35 U.S.C. 112, first paragraph insufficient written description, for the reasons stated in the prior action, is maintained. In addition, new Claims 27-36 are herein rejected under 35 U.S.C. 112, first paragraph insufficient written description, for the same reasons.

In support of their request that said rejection be withdrawn, Applicants provide the following argument. The written description requirement does not require the specification to disclose each and every embodiment encompassed by a claim, but that the skilled artisan be enabled to make and use the encompassed embodiments without undue experimentation.

This argument is not found to be persuasive for the following reasons. Respectfully, Applicants appear to be confusion the requirement for enablement with the requirement for written description. MPEP 2161 states:

The written description requirement is separate and distinct from the enablement requirement. In *re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) (While acknowledging that some of its cases concerning the written description requirement and the enablement requirement are confusing, the Federal Circuit reaffirmed that under 35 U.S.C. 112, first paragraph, the written description requirement is separate and distinct from the enablement requirement and gave an example thereof.). An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See *In re Armbruster*, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975) (“[A] specification which describes’ does not necessarily also enable’ one skilled in the art to make or use the claimed invention.”). Best mode is a separate and

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distinct requirement from the enablement requirement. *In re Newton*, 414 F.2d 1400, 163 USPQ 34 (CCPA 1969).

MPEP 2162 states:

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *> Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *< Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

Because the specification fails to disclose any polynucleotide encoding any polypeptide having ribosome-inactivating activity, or any description of the structure of any said polynucleotide, the skilled artisan cannot reasonably conclude that the Inventors had possession of the claimed invention at the time of filing. For these reasons and those explained in the prior action, Claims 11-20 and 27-36 are rejected under 35 U.S.C. 112, first paragraph for insufficient written description.

Claims 29, 32, and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Inventors, at the time the application was filed, had possession of the claimed invention. Claims 29, 32, and 35 introduce the limitation of a polynucleotide encoding a protein comprising or consisting of a polypeptide having at least 75% homology to SEQ ID NO: 9. The specification fails to describe said limitation and, thus, Claims 29, 32, and 35 are rejected under 35 U.S.C. 112, first paragraph, for introducing New Matter.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
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SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER